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U.S.

A Pain-Drug Champion Has Second Thoughts

By Thomas Catan and Evan Perez

Updated Dec. 17, 2012 11:36 a.m. ET

It has been his life's work. Now, Russell Portenoy appears to be having second thoughts.

Two decades ago, the prominent New York pain-care specialist drove a movement to help people with chronic pain. He campaigned to rehabilitate a group of painkillers derived from the opium poppy that were long shunned by physicians because of their addictiveness.

Dr. Portenoy's message was wildly successful. Today, drugs containing opioids like Vicodin, OxyContin and Percocet are among the most widely prescribed pharmaceuticals in America.

Opioids are also behind the country's deadliest drug epidemic. More than 16,500 people die of overdoses annually, more than all illegal drugs combined.

Now, Dr. Portenoy and other pain doctors who promoted the drugs say they erred by overstating the drugs' benefits and glossing over risks. "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did," Dr. Portenoy said in an interview with The Wall Street Journal. "We didn't know then what we know now."

Recent research suggests a significantly higher risk of addiction than previously thought, and questions whether opioids are effective against long-term chronic pain.

The change of heart among former champions of opioid use has happened quietly, largely beyond the notice of many doctors. New York psychiatrist Joseph Carmody said he was "shocked" after attending a recent lecture outlining the latest findings on opioid risk.

"It goes in the face of everything you've learned," he said. "You saw other doctors come around to it and saying, 'Oh my God, what are we doing?'"

Because doctors feared they were dangerous and addictive, opioids were long reserved mainly for cancer patients. But Dr. Portenoy argued that they could be also safely be taken for months or years by people suffering from chronic pain. Among the assertions he and his followers made in the 1990s: Less than 1% of opioid users became addicted, the drugs were easy to discontinue and overdoses were extremely rare in pain patients.

Many of those experts now say those claims were weren't based on sound scientific evidence. "I gave innumerable lectures in the late 1980s and '90s about addiction that weren't true," Dr. Portenoy said in a 2010 videotaped interview with a fellow doctor. The Journal reviewed the conversation, much of which is previously unpublished.

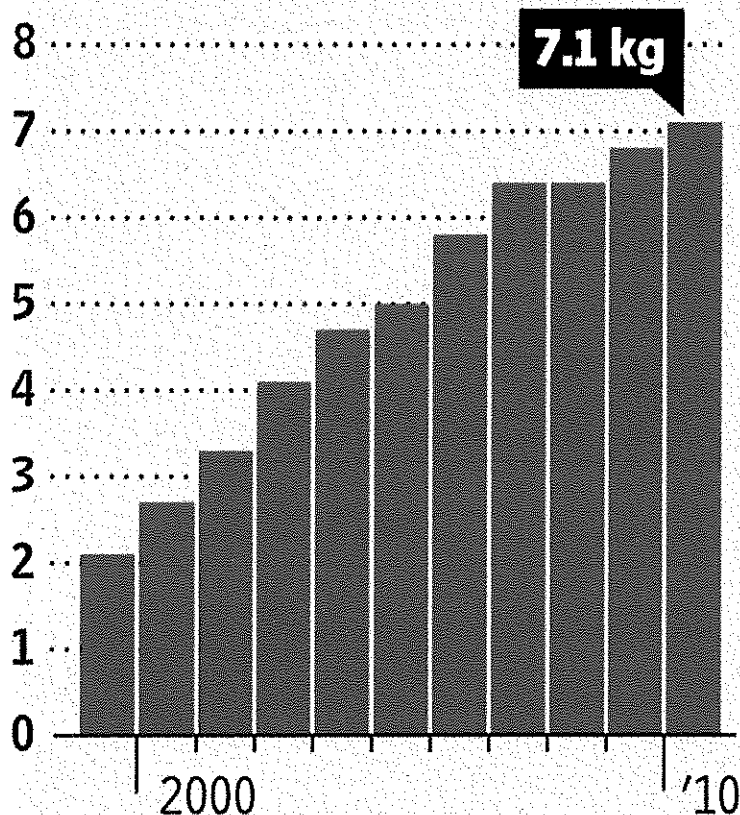
In it, Dr. Portenoy said it was "quite scary" to think how the growth in opioid prescribing driven by people like him had contributed to soaring rates of addiction and overdose deaths. "Clearly, if I had an inkling of what I know now then, I wouldn't have spoken in the way that I spoke. It was clearly the wrong thing to do," Dr. Portenoy said in the recording.

Speaking to the Journal in September, Dr. Portenoy tempered that statement with cautions about overturning what he sees as the positive change he achieved. He cited his 82-year-old mother, who has taken hydrocodone to control arthritis for 15 years. "If you insist on regulation, then you're consigning my mother and many millions of people like my mother to live in chronic pain," he said.

Virtually no one wants to return to a time when doctors were reluctant to use opioids even for cancer patients. All sides also agree that there is a group of people who do well on opioids long-term, taming their pain while avoiding addiction or excessive sedation, although there is no research on how large this group is or how to identify them before they begin a treatment. There is also widespread agreement that they can be used, with caution, for acute pain, such as after an operation.

On the Rise

Kilograms of opioids sold,
per 10,000 people



Source: National Vital Statistics

But some specialists now question whether the drugs should be prescribed so freely for months or years to people with chronic pain that isn't related to cancer, as Dr. Portenoy proposed 25 years ago. "People lost sight of the fact that these are dangerous drugs that are highly addictive," said Jane Ballantyne, a pain specialist at the University of Washington. She once agreed with Dr. Portenoy and proponents of broad opioid use but now believes they need to be used more selectively.

Opium-derived painkillers have been

around for thousands of years. Early in the 20th century, heroin was sold as a cough suppressant. Heroin addiction in the U.S. skyrocketed. Congress banned the drug in 1924 and doctors became deeply wary about using opioids.

Dr. Portenoy set out to change that. As a young doctor at Memorial Sloan-Kettering hospital in New York, he noticed that opioids were effective in cancer patients with terrible pain.

In 1986, at the age of 31, he co-wrote a seminal paper arguing that opioids could also be used in the much larger group of people without cancer who suffered chronic pain. The paper was based on just 38 cases and included several caveats.

Nevertheless, it opened the door to much broader prescribing of the drugs for more common complaints such as nerve or back pain.

Charming and articulate, he became a sought-after public speaker. He argued that opioids are a "gift from nature" that were being forsaken because of "opiophobia" among doctors. "We had to destigmatize these drugs," said Dr. Portenoy.

He rose to chairman of pain medicine and palliative care at Beth Israel Medical Center in New York. His small office is studded with awards and evidence of his offbeat sense of humor. He prominently displays a magazine mock-up that jokingly dubs him "The King of Pain."

At medical conferences, his confident, knowing manner helped smooth the way for his message. Before an audience of government regulators, he once joked that he might tell a patient at low risk of abuse: "Here, [have] six months of drugs. See you later," he said, according to a Food and Drug Administration transcript. Amid laughter, he added, "It's just hyperbole. I don't actually do that."

Steven Passik, a psychologist who once worked closely with Dr. Portenoy and describes him as his mentor, says their message wasn't based on scientific evidence so much as a zeal to improve patients' lives. "It had all the makings of a religious movement at the time," he says. "It had that kind of a spirit to it."

Drug companies took notice. In 1996, Purdue Pharma LP released OxyContin, a form of oxycodone in a patented, time-release form, and rivals followed suit. Today, sales of opioid painkillers total more than \$9 billion a year, according to IMS Health, which tracks sales for drug companies.

In 2007, Purdue Pharma and three executives pleaded guilty to "misbranding" of the drug as less addictive and less subject to abuse than other pain medicines and paid \$635 million in fines.

Purdue Pharma says it has worked to discourage abuse of its drugs, adding that OxyContin is safe and effective when used properly.

In the late 1990s, groups such as the American Pain Foundation, of which Dr. Portenoy was a director, urged tackling what they called an epidemic of untreated pain. The American Pain Society, of which he was president,

campaigned to make pain what it called the "fifth vital sign" that doctors should monitor, alongside blood pressure, temperature, heartbeat and breathing.

Dr. Portenoy helped write a landmark 1996 consensus statement by two professional pain societies that said there was little risk of addiction or overdose among pain patients. In lectures he cited the statistic that less than 1% of opioid users became addicted.

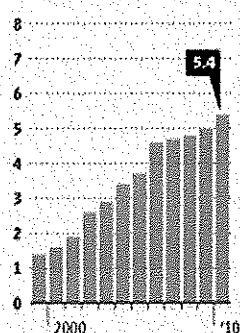
Today, even proponents of opioid use say that figure was wrong. "It's obviously crazy to think that only 1% of the population is at risk for opioid addiction," said Lynn Webster, president-elect of the American Academy of Pain Medicine, one of the publishers of the 1996 statement. "It's just not true."

The figure came from a single-paragraph report in the New England Journal of Medicine in 1980 describing hospitalized patients briefly given opioids. Dr. Portenoy now says he shouldn't have used the information in lectures because it wasn't relevant for patients with chronic noncancer pain.

For such a widely used therapy, there is relatively little scientific evidence that opioid drugs are safe and effective for long-term use. "Data about the effectiveness of opioids does not exist," Dr. Portenoy said in his recent Journal interview. To get a painkiller approved, companies must prove that it is better at reducing pain than a sugar pill during short trials often lasting less than 12 weeks.

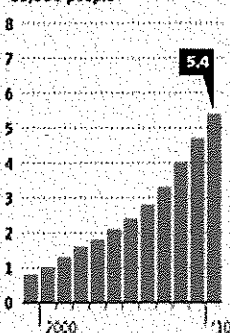
The Opioid Toll

Opioid-related deaths, per 100,000 people



Source: National Vital Statistics

Admissions for treatment of opioid addiction, per 10,000 people



The Wall Street Journal

"Do they work for five years, 10 years, 20 years?" Dr. Portenoy said in the Journal interview. "We're at the level of anecdote." Even so, he says, the drugs can still benefit carefully selected patients.

Dr. Portenoy's ideas about opioids reached into mainstream medicine and attracted outspoken advocates. In a 1998 talk in Houston, Alan Spanos, a South Carolina pain specialist, said patients with chronic noncancer pain could be

trusted to decide themselves how many painkillers to take without risk of overdose. According to a recording, Dr. Spanos said he understood that a patient would simply "go to sleep" before stopping breathing. While asleep, he said, the

patient "can't take a dangerous dose. It sounds scary, but as far as I know, nobody anywhere is getting burned by doing it this way."

Dr. Spanos declined to say whether he still agreed with his previous statements. He said opioids can be helpful and safe with proper use.

One of Dr. Portenoy's chief complaints was that doctors were reluctant to prescribe opioids because they feared scrutiny by regulators or law enforcement. In the second half of the 1990s, he and his followers campaigned successfully for policies to change that.

In 1998, the Federation of State Medical Boards released a recommended policy reassuring doctors that they wouldn't face regulatory action for prescribing even large amounts of narcotics, as long as it was in the course of medical treatment. In 2004 the group called on state medical boards to make undertreatment of pain punishable for the first time.

That policy was drawn up with the help of several people with links to opioid makers, including David Haddox, a senior Purdue Pharma executive then and now. The federation said it received nearly \$2 million from opioid makers since 1997. The federation says it derives the majority of its funding from administering medical licensing exams, credential verification, and data services.

A federation-published book outlining the opioid policy was funded by opioid makers including Purdue Pharma, Endo Health Solutions Inc. and others, with proceeds totaling \$280,000 going to the federation. Endo declined to comment.

Purdue Pharma said, "Dr. Haddox was recruited by the FSMB, so he did not have undue or inappropriate influence" on the federation's output. Purdue declined to make Dr. Haddox available to comment.

The federation said it didn't believe its model policy contributed to increased prescriptions and said drug makers didn't influence its guidelines.

In 2001, the Joint Commission, which accredits U.S. hospitals, issued new standards telling hospitals to regularly ask patients about pain and to make treating it a priority. The now-familiar pain scale was introduced in many hospitals, with patients being asked to rate their pain from one to 10 and circle a smiling or frowning face.

The Joint Commission published a guide sponsored by Purdue Pharma. "Some clinicians have inaccurate and exaggerated concerns" about addiction, tolerance and risk of death, the guide said. "This attitude prevails despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control."

Purdue said the booklet emerged from a process that "represented the consensus of a broad range of interested stakeholders." Drug makers regularly pay for educational materials for physicians as an element of their marketing.

The Joint Commission said its standards didn't encourage physicians and hospitals to increase prescriptions. "I think that's a very distorted and not helpful explanation of what's going on," said Ana McKee, the Joint Commission's chief medical officer.

Over his career, Dr. Portenoy has disclosed relationships with more than a dozen companies, most of which produce opioid painkillers. "My viewpoint is that I can have those relationships, they would benefit my educational mission, they benefit in my research mission, and to some extent, they can benefit my own pocketbook, without producing in me any tendency to engage in undue influence or misinformation," he said.

Dr. Portenoy and Beth Israel declined to provide details of their funding by drug companies. A 2007 fundraising prospectus from Dr. Portenoy's program shows that his program received millions of dollars over the preceding decade in funding from opioid makers including Endo, Abbott Laboratories, Cephalon, Purdue Pharma and Johnson & Johnson.

Endo, Abbott, Janssen and Purdue declined to comment. Cephalon's current owner, Teva Pharmaceutical Industries Ltd., didn't immediately have a comment.

In May of this year, the Senate Finance Committee opened an investigation into the financial ties between the pharmaceutical makers and the doctors and groups that advocated broader use of opioids. It asked opioid makers to disclose how much they had paid Dr. Portenoy, his program and several organizations he was involved with.

After spending most of his professional life advocating greater use of the drugs, Dr. Portenoy said there is still little research to show whether patients who embark on long-term opioid therapy will ever be able to stop.

Earlier this year, he said, he asked his mother whether she would stop taking her hydrocodone as part of a scientific study. She said no.

"How difficult is it for her to get off these drugs?" Dr. Portenoy asked. "You have no idea and neither do I, because no one knows."

—Devlin Barrett contributed to this article.

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Corrections & Amplifications

In the United States in 2010, there were 5.4 opioid-related deaths per 100,000 people and 5.4 admissions for treatment of opioid addiction per 10,000 people. An earlier version of a graphic accompanying this article reversed the labels on the two charts.

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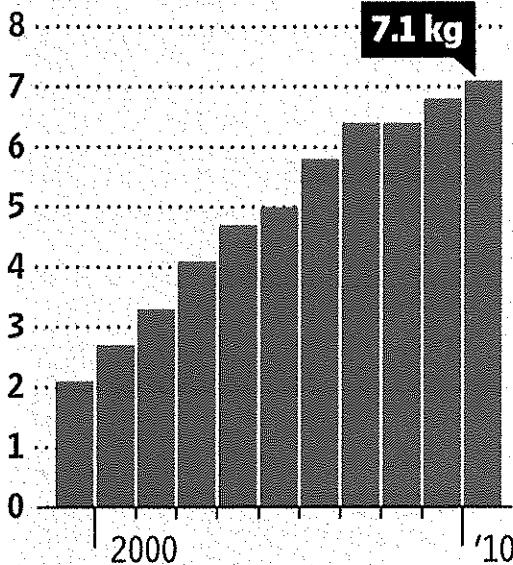
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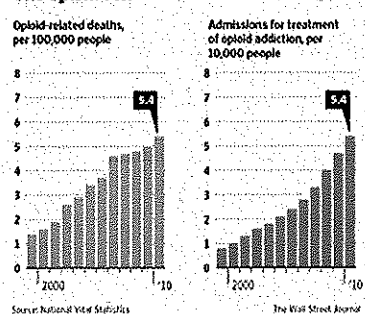
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